

### **REMARKS/ARGUMENTS**

Claims 1-12 are pending in the subject application. Claims 1-12 presently stand rejected. Claims 1, 3, 4, 6, and 8 have been amended by the present amendment. No new matter is added by way of claim amendment. Claims 9, 10, and 11 have been canceled without prejudice to or disclaimer of the subject matter encompassed thereby. New claims 13-18 have been added by the present amendment. No new matter has been added by way of presentation of these new claims. Therefore, upon entry of the present amendment, claims 1-8, 12-18 will remain pending in the subject application. Reexamination and reconsideration of the claims are respectfully requested in view of these amendments and the following remarks. The Examiner's comments in the Office Action are addressed below in the order set forth therein.

#### **The Rejection of Claims 1-7, and 12 under 35 U.S.C. § 102**

##### **Should Be Withdrawn**

Claims 1, 3-5, and 12 have been rejected under 35 U.S.C. § 102(a) as allegedly being anticipated by Foley. Applicants respectfully submit that the compounds disclosed in Foley have an alkyl substituent group, specifically exemplified as an n-butyl group, at the 3-position of the xanthine ring. In contrast, the substituent group at the 3-position of the xanthine ring of the compounds recited in claims 1, 3-5, and 12 is represented by an “-(CH<sub>2</sub>)-A'-R<sub>4</sub>” group, wherein A' must be an aromatic or heteroaromatic ring. Accordingly, Applicants respectfully submit that the compounds recited in claims 1, 3-5, and 12 of the subject application cannot be anticipated by Foley. Therefore, Applicants respectfully request that the rejection of claims 1, 3-5, and 12 under 35 U.S.C. § 102(a) with respect to Foley be withdrawn at this time.

Claims 1, 3-5, and 12 have been rejected under 35 U.S.C. § 102(e) as allegedly being anticipated by Dunten. Applicants have amended claim 1 by defining the variable A' in the group -(CH<sub>2</sub>)-A'-R<sub>4</sub>-, which is at the 3-position of the xanthine ring, to be a 6-membered aromatic or heteroaromatic ring. Applicants respectfully submit that Dunten does not disclose xanthine compounds having a -(CH<sub>2</sub>)-A'-R<sub>4</sub>- substituent group, wherein

A' is a 6-membered aromatic or heteroaromatic ring, at the 3-position of the xanthine ring. Accordingly, Applicants respectfully submit that the compounds recited in claim 1 of the subject application as presently amended cannot be anticipated by Dunten. Therefore, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 102(e) with respect to Dunten be withdrawn at this time.

Further, Applicants note that claims 3-5 and 12 depend from independent claim 1. For the reasons stated immediately hereinabove, the compounds recited in claim 1 as presently amended cannot be anticipated by Dunten. Thus, the compounds and compositions recited in claims 3-5 and 12 cannot be anticipated by Dunten. Therefore, Applicants respectfully request that the rejection of claims 3-5 and 12 under 35 U.S.C. § 102(e) with respect to Dunten be withdrawn at this time.

Claims 1-7 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Thyrion. Applicants have amended claim 1 and claim 3 by deleting the variable "R<sub>2</sub>" from the list of substituent groups that can include a C<sub>1</sub>-C<sub>8</sub> alkanyl group. Said another way, the variable R<sub>2</sub> in amended claim 1 and amended claim 3 cannot be alkyl. Accordingly, Applicants respectfully submit that the compounds recited in claim 1 and claim 3 of the subject application as presently amended cannot be anticipated by Thyrion, which requires R<sub>2</sub> to be methyl. Therefore, Applicants respectfully request that the rejection of claim 1 and claim 3 under 35 U.S.C. § 102(b) with respect to Thyrion be withdrawn at this time.

Further, because claims 2, and 4-7 ultimately depend from claim 1, Applicants respectfully submit that, for the reasons stated immediately hereinabove, the compounds disclosed in claims 2, and 4-7 also cannot be anticipated by Thyrion. Therefore, Applicants respectfully request that the rejection of claims 2, and 4-7 under 35 U.S.C. § 102(b) with respect to Thyrion be withdrawn at this time.

Claims 1-7 and 12 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Krantz, Suzuki, and Connell. As mentioned immediately hereinabove, claim 1 and claim 3 have been amended so that the variable R<sub>2</sub> cannot be alkyl. Accordingly, Applicants respectfully submit that the compounds recited in claim 1 and

claim 3 of the subject application as presently amended cannot be anticipated by Krantz, Suzuki, or Connell, each of which requires R<sub>2</sub> to be H or alkyl. Therefore, Applicants respectfully request that the rejection of claim 1 and claim 3 under 35 U.S.C. § 102(b) with respect to Krantz, Suzuki, and Connell be withdrawn at this time.

Further, because claims 2, 4-7, and 12 ultimately depend from claim 1, Applicants respectfully submit that, for the reasons stated immediately hereinabove, the compounds and compositions disclosed in claims 2, 4-7, and 12 also cannot be anticipated by Krantz, Suzuki, and Connell. Therefore, Applicants respectfully request that the rejection of claims 2, 4-7 and 12 under 35 U.S.C. § 102(b) with respect to Krantz, Suzuki, and Connell be withdrawn at this time.

Claims 1-7 have been rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by Neely. Applicants have amended claim 1 by defining the variable "A" to be a 5- or 6-membered heteroaromatic ring containing 1 to 4 heteroatoms selected from the group consisting of N, O, and S. Applicants note that the equivalent of variable "A" in the compounds disclosed in Neely must be phenyl, i.e., a divalent C<sub>6</sub>H<sub>4</sub> group. Accordingly, Applicants respectfully submit that the compounds recited in claim 1 of the subject application as presently amended cannot be anticipated by Neely. Therefore, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 102(b) with respect to Neely be withdrawn at this time.

Applicants also have amended claim 4 and claim 6 by defining the variable "A" recited therein to be selected from the group consisting of pyridyl, thiophenyl, thiazolyl, and tetrazolyl. Support for this amendment can be found, inter alia, in Examples 5, 6, 7, and 8 of the subject application as filed. No new matter has been added. Applicants respectfully submit that the compounds recited in claim 4 and claim 6 cannot be anticipated by Neely, which requires the variable "A" to be phenyl. Therefore, Applicants respectfully request that the rejection of claim 4 and 6 under 35 U.S.C. § 102(b) with respect to Neely be withdrawn at this time.

Further, because claims 2-3, 5, and 7 ultimately depend from claim 1, Applicants respectfully submit that, for the reasons stated immediately hereinabove, the compounds

disclosed in claims 2-3, 5, and 7 also cannot be anticipated by Neely. Therefore, Applicants respectfully request that the rejection of claims 2-3, 5, and 7 under 35 U.S.C. § 102(b) with respect to Neely be withdrawn at this time.

Applicants also have canceled claims 9, 10 and 11 and deleted compounds recited in claim 8 wherein the variable A is phenyl as compounds in which the variable A is phenyl are no longer within the scope of amended claim 1 from which claims 8-11 depend. Applicants also have amended claim 8 by inserting compounds from original claim 9 in which the variable A is a heteroaromatic group, e.g., thiophen-2-yl and 1H-tetrazol-5-yl. Support for this amendment can be found in original claim 9. No new matter has been added.

In view of the present amendments and remarks, Applicants respectfully submit that claims 1-7 and 12 are in condition for allowance and respectfully request the same.

The Rejection of Claims 1-12 under 35 U.S.C. § 112, Second Paragraph,  
Should Be Withdrawn

Claims 1-12 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The Office Action lists seven points for rejecting the claims. Each point is addressed below in the order it appears in the Office Action:

1. The Office Action contends that the definition of  $R_1/R_2$  is unclear. Applicants have amended claim 1 and claim 3 by deleting the reference to the variable " $R_2$ " in the alternative. Applicants respectfully submit that the definitions of  $R_1$  and  $R_2$  as recited in presently amended claim 1 and claim 3 satisfy the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the rejection of claim 1 and 3 under 35 U.S.C. § 112, second paragraph, in reference to the definitions of  $R_1$  and  $R_2$  be withdrawn at this time.
2. The Office Action asserts that for " $R_{15}$  [sic] and  $R_{15}$ ," the first term should be "alkylene," not alkyl. Applicants note that it appears that the Examiner intended to

refer to the variables **R14** and R15. Accordingly, Applicants have amended claim 1 by deleting the term “alkyl” from the definition of R<sub>14</sub> and R<sub>15</sub> and inserting the term “alkylene.” Applicants respectfully submit the definitions of R<sub>14</sub> and R<sub>15</sub> as recited in presently amended claim 1 satisfy the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, in reference to the definitions of R<sub>14</sub> and R<sub>15</sub> be withdrawn at this time.

3. The Office Action contends that the variable “A” as recited in claim 4 and claim 6 is unclear. Applicants respectfully submit that, because claim 4 depends from claim 1, the variable “A” in claim 4 is the same as “A” in claim 1. Likewise, the variable “A” in claim 6 is the same as “A” in claim 1. Applicants note that the second use of the variable “A” in claim 1 is actually an “A prime,” e.g., A', as the variable is used in formula (i). Applicants respectfully submit that claim 4 and claim 6 as presently presented satisfy the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully request that the rejection of claim 4 and claim 6 under 35 U.S.C. § 112, second paragraph, in reference to the variable “A” be withdrawn at this time.

4. The Office Action contends that the formula at page 5, line 6 is unclear. As provided herein below, the portion of claim 1 including the structure in question has been deleted. Accordingly, Applicants respectfully submit that this rejection of claim 1 under 35 U.S.C. § 112, second paragraph, is rendered moot. Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, in reference to the formula at page 5, line 6, be withdrawn at this time.

5. The Office Action contends that at the first line of page 6, it is unclear if the “a benzyl- or phenyl- ...” refers to an additional choice for R<sub>8</sub> or is a substituent group on the alkyl, alkenyl or alkynyl. As provided herein below, the portion of claim 1 including the phrase objected to by the Examiner has been deleted, rendering moot the rejection of claim 1 under U.S.C. § 112, second paragraph, in reference to the phrase “a benzyl- or phenyl-....” Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, in reference to the phrase “a benzyl- or phenyl-

....” be withdrawn at this time.

6. The Office Action contends that the term “preferably” in relation to the variables R6 and R7 is improper alternative language. Applicants have amended claim 1 by deleting the phrase including the term “preferably” rendering moot the rejection of claim 1 under U.S.C. § 112, second paragraph, in reference to the term “preferably.” Accordingly, Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 112, second paragraph, in reference to the term “preferably” be withdrawn at this time.

7. The Office Action questions the use of the term “substituted” in the definition of R<sub>6</sub>. Applicants have amended claim 1 by deleting the first occurrence of the term “substituted” in the definition of R<sub>6</sub> and amending the definition of R<sub>6</sub> to read “amino substituted with C<sub>1</sub>-to-C<sub>8</sub> alkyl....”

In sum, Applicants respectfully submit that claims 1-8 and 12 as presently amended satisfy the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicants respectfully submit that claims 1-8 and 12 are in condition for allowance and respectfully request the same.

The Rejection of Claims 1-12 under 35 U.S.C. § 112, First Paragraph,  
Should Be Withdrawn

Claims 1-12 have been rejected under 35 U.S.C. § 112, first paragraph, under the contention that the specification allegedly does not provide enablement for hydrates. Applicants respectfully submit that “[a] patent need not teach ... what is well known in the art.” MPEP § 2164.01 (citing In re Buchner, 929 F.2d 660, 661, 18 USPQ2d 1331, 1332 (Fed. Cir. 1991); Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384, 231 USPQ 81, 94 (Fed. Cir. 1986)). Applicants respectfully submit that the formation of hydrates of xanthine derivatives is well known in the art. For example, Applicants note that U.S. Patent No. 4,879,296, attached hereto as **Appendix A**, discloses hydrates of a number of xanthine derivatives. See, for example, col. 4, lines 48-51, which disclose that solvates of the xanthine compounds disclosed therein can include a hydrate. Also see Example 1, col. 14, lines 7-12, and Example 2, col. 14, lines 27-29, which describe the

formation of a monohydrate from the xanthine compounds disclosed therein. Therefore, Applicants respectfully submit that in view of what is well known in the art, the specification is enabling for the formation of hydrates of the presently disclosed xanthine compounds. Thus, Applicants respectfully request that the rejection of claims 1-12 under 35 U.S.C. § 112, first paragraph, be withdrawn at this time.

The Provisional Rejection of Claims 1-12 for Double Patenting  
Should Be Withdrawn

Claims 1-12 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-20 of copending application serial no. 10/861,677 (hereinafter “the ‘677 application”) for the reasons stated in the Office Action. Without acquiescing to the grounds of the double patenting rejection, Applicants note that the copending applications are still in the process of examination. Thus, it is not yet known which of these applications will be the first to be allowed for issuance as a patent. Should the copending ‘677 application be the first to be in condition for allowance, Applicants will, upon notification to this effect, either argue the double-patenting rejection or timely file a terminal disclaimer in the present application. Applicants therefore respectfully submit that they have responded appropriately to this provisional rejection and request that this rejection be withdrawn at this time.

Clarifying Amendments

Applicants have made the following clarifying, non-limiting amendments. To better define the scope of the presently claimed subject matter, Applicants have amended claim 1 by inserting the group “COOH” in the definition of R<sub>4</sub>. Support for this amendment can be found in Example 12. No new matter has been added. Applicants also have amended the definition of R<sub>4</sub> in claim 1 by deleting the comma between the phrase “1 to 8 carbon atoms” and the term “halo” and inserting a semicolon. Applicants also have replaced the term “denotes” throughout claim 1 with the term “is” or “are,” as appropriate. Further, in a clarifying amendment, Applicants have amended claim 1 by deleting portions

of the definitions of R<sub>1</sub>, R<sub>7</sub>, and R<sub>8</sub> and combining the definitions of R<sub>6</sub>, R<sub>7</sub>, and R<sub>8</sub>. Applicants also have deleted the terms "NHCONH phenyl" from the definition of R<sub>1</sub>. Applicants also have amended the definition of R<sub>1</sub> in claim 1 to reflect that numbers in the term "C2-C8," which modifies the phrase "alkynyl- group," should be subscripts. Applicants note that these clarifying amendments have been made to expedite prosecution of the subject application without prejudice to or disclaimer of the subject matter encompassed thereby.

#### New Claims

Applicants have added new claims 13-18 by the present amendment. New claim 13 is directed toward embodiments of compounds of formula (I) wherein the variable "A" is a 5- or 6-membered aromatic ring. Further, the variable R<sub>4</sub> in new claim 13 is defined to include NH<sub>2</sub>, halo, NHR<sub>8</sub>, NR<sub>8</sub>R<sub>9</sub>, NHCOR<sub>8</sub>, NR<sub>8</sub>COR<sub>9</sub>, COOH, SO<sub>3</sub>H and PO<sub>3</sub>H<sub>2</sub>. Applicants note that such substituent groups are not disclosed in Neely. Support for new claim 13 can be found in claim 1 as originally filed. No new matter has been added.

New claim 14 is directed toward embodiments of compounds of formula (I) wherein A is phenyl. Support for new claim 14 can be found in original claim 4. No new matter has been added.

New claim 15 is directed toward embodiments of compounds of formula (I) wherein A' is phenyl. Support for new claim 15 can be found in original claim 5. No new matter has been added.

New claim 17 is directed toward specific compounds of formula (I), wherein A is a 5- or 6-membered aromatic ring. Support for new claim 17 can be found in original claims 8-11. No new matter has been added.

New claim 18 is directed toward a composition comprising a compound of claim 13 in a pharmaceutically acceptable carrier. Support for new claim 18 can be found in original claim 12. No new matter has been added. Applicants respectfully submit that no new matter has been added by way of presentation of new claims 13-18. Applicants respectfully submit that claims 13-18 are in condition for allowance and respectfully request the same.

Appl. No.: 10/780,296  
Amdt. dated June 6, 2006  
Reply to Office Action of February 6, 2006

### CONCLUSION

In view of the aforementioned amendments and remarks, Applicants respectfully submit that the rejections of the claims under 35 U.S.C. §102; §112, first paragraph; and §112, second paragraph, are now overcome. Applicants respectfully submit that this application is now in condition for allowance. Early notice to this effect is solicited. If in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject Application, the Examiner is invited to call the undersigned.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

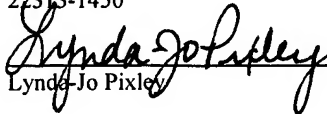


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